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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,744	02/02/2004	Christopher Hunter	120-000220US	4909

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,744	HUNTER ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12,20,21,24-26,74 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11,12,20,21,24-26,74, and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. Applicant's Response filed 11/18/2010 is acknowledged and entered. Claims 2-6, 7-10, 13-19, 22-23, and 27-73 have been cancelled by Applicant. Claims 1, 11, 12, 20,21, 24-26, 74, and 75 are pending and under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/18/2010 has been considered by the examiner. A signed copy is attached.

Response to Arguments/Amendments

Claim of Benefit and Rejections Maintained

Benefit

3. Applicant repeats arguments that have been raised multiple times, directed toward the claim of benefit. As previously stated in the Office Action mailed 6/16/2010, during the Interview held on 2 February 2010, the Examiner stated that she would once again review and consider Applicant's claim of benefit (see also Applicant's Remarks filed 3/18/2010, page 8). After additional consideration, Applicant's claim for benefit to provisional application 60/44,494, filed 31 January 2003, and provisional application 60/519,074, filed 10 November 2003, remains proper. However, benefit cannot be accorded to the provisional filings for the reasons set forth in detail of record. The denial of benefit, as stated in the Office Action of 11/29/2006 (page 4), is based on the fact that the scope of the provisional applications fails to correspond to the scope of the claims, as written. This is the nexus of the lack of enabling disclosure of the provisional applications to provide adequate support for the instantly claimed invention. See also the very detailed discussions in the Office Action mailed 8/9/2007, pages 2 and 3; the Office Action mailed 2/26/2008, pages 2-5, especially page 5; and the Office Action mailed 11/21/2008, pages 2-4. No claim amendments have been made in the response filed 11/18/2010 necessitating further consideration of Applicant's claim of benefit. Benefit remains accorded to the instant filing date of 2 February 2004.

Provisional Obviousness-Type Double Patenting Rejection

4. The provisional rejection of claims 1, 11, 12, 20, 23, 74, and 75 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 of copending Application No. 11/880,121, is maintained for the reasons of record.

Applicant's response filed 11/18/2010 appears to be largely cut-and-pasted from prior responses, as the examiner has expressly and unambiguously responded to Applicant's statement and arguments, yet those very same statements and arguments are repeated in the 11/18/2010 response. As previously Applicant states that "the examiner has requested that a terminal disclaimer be filed." Applicant's statement is and remains inaccurate. The examiner requires, pursuant to regulations, that a complete response be made to each rejection, including the instant provisional ODP rejection. Applicant is free to choose whether that response comprises argument and reasons why the rejection should not be maintained or whether to file a Terminal Disclaimer to obviate the rejection. Applicant has stated of record and has reiterated in the Remarks on page 10, that a Terminal Disclaimer will be filed over the claims of the '121 application when the instant claims are in condition for allowance. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 11, 12, 20, 21, 24-26, 74, and 75 remain rejected under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by Timans et al., US Patent Application Publication 2002/0164609 A1 (publication date 7 November 2002) now US Patent 7,148,330 (12 December 2006, filed 30 November 2001), for the reasons of record and the reasons set forth herein.

Applicant continues to make arguments that have been previously presented and responded to. Applicant is advised that this is not an efficient use of time or resources and it does not further or otherwise promote compact prosecution. These issues have been discussed at length in the file wrapper and in Interviews.

Applicant argues that the prior art must show a patient needing suppression of a T-helper cell mediated immune response and that patient is administered an effective amount of an IL-27R agonist selected from the group consisting of IL-27, an active fragment of IL-27, an agonistic antibody, and an IL-27R binding antibody fragment that enhances Il-27R activity (Remarks, p.3). Applicant's argument has been fully considered, but it is not persuasive. The claims, as written, are not so limited. The patient population is "a patient with immune hyperactivity" (compare claims 1, 20, and 21). The subject population in claim 24 is "a patient in need thereof." The immune hyperactivity in claim 74 is T-helper cell mediated immune hyperactivity. The immune hyperactivity in claim 75 is interferon-gamma (IFNγ)-mediated immune hyperactivity.

Applicant argues that the prior art references must specify the type of condition for which a patient is being treated and with which compounds that patient is treated. Applicant also argues that in order to support an anticipation rejection over the claimed invention, it is insufficient for a reference to merely disclose all the compositions involved in the claimed methods. Applicant's arguments are not persuasive because they continue to disregard the express teachings of Timans. As stated of record, Timans teaches the administration of IL-27 in the treatment of immune disorders and inflammation (paragraphs 14, 24, 36, 39, 42, 43, 161, and 204; see especially paragraph 39). Therapeutic administration in humans is taught at paragraphs 48 and 134. Diagnosis of subjects with an inflammatory condition as a prerequisite to administration is taught at paragraphs 128-133. Additionally, Applicant's attention is drawn to the fact that Timans teaches the use of IL-27 to treat inflammation (i.e. immune hyperactivity) at paragarph 39.

Applicant argues that no data is provided in Timans that could support the idea that all of p28, IL-27, WSX-1, and WSX-1 antagonists can or should be used to treat both immune deficiencies and inflammation (Remarks, pp. 3 to 4). Applicant's arguments continue to parse the various embodiments taught in Timans in ways that are preferential to Applicant by attempting to minimize some embodiments and profess that other embodiments are the real concern of Timans. Applicant's arguments in this regard have previously been presented and considered. Timans teaches what he teaches and the examiner has considered the teachings as both individual embodiments and the teachings as a whole. It was previously explained to Applicant that some cytokines, including IL-27, and their receptors (especially receptors that

share multiple promiscuous subunits) are known to be pleiotropic in their activities and functions. Many cytokines are redundant in their activities and they are also regulated by a wide variety of immune, endocrine, autocrine, paracrine, and juxtacrine mechanisms. Applicant is asking the examiner to consider facts not in evidence in Timans, that one cytokine has only one function and cannot function in any other way. This simply isn't how cytokines, let alone IL-27, work. Applicant has offered no evidence or data or anything other than attorney argument to make assumptions about the teachings in Timans.

Applicant argues "it is clear that Timans did not teach or suggest that one should administer a composition comprising IL-27 to a patient with an inflammatory condition. Applicant's argument is directly contradicted by paragraph 39 of Timans. This paragraph has been discussed of record on multiple occasions and was discussed in the Interview. Paragraph 39 is what it is, regardless of how Applicant chooses to interpret it.

Applicant points to paragraph 161 in support of the argument that Timans really intends to teach antagonists of the IL-27R and not agonists as instantly claimed. This argument has also been addressed of record and in the Interview. Timans teach both agonists and antagonists of IL-27R. Applicant is again emphasizing one embodiment over another taught by Timans. These arguments have been addressed of record and above.

7. Claims 1, 11, 12, 20, 21, 24-26, 74, and 75 remain rejected under 35 U.S.C. 102(b) as being anticipated by DeSauvage et al., WO 01/29070 (26 April 2001) (see also US Patent Application Publication 2004/0234522 A1) for the reasons of record and for the reasons set forth herein.

As stated above, Applicant continues to make arguments that have been previously presented and responded to.

Applicant argues that the prior art must show a patient needing suppression of a T-helper cell mediated immune response and that patient is administered an effective amount of an IL-27R agonist selected from the group consisting of IL-27, an active fragment of IL-27, an agonistic antibody, and an IL-27R binding antibody fragment that enhances Il-27R activity (Remarks, p.3). Applicant's argument has been fully considered, but it is not persuasive. The claims, as written, are not so limited. The patient population is "a patient with immune hyperactivity" (compare claims 1, 20, and 21). The subject population in claim 24 is "a patient in need thereof." The immune hyperactivity in claim 74 is T-helper cell mediated immune hyperactivity. The immune hyperactivity in claim 75 is interferon-gamma (IFNγ)-mediated immune hyperactivity.

Applicant asks the examiner to point out where on pp. 59-63 WSX-1 polypeptides and antibodies should be used to treat immune hyperactivity (Remarks, p. 5). On page 59, under the heading "Methods of Treatment" DeSauvage states that "[i]t is contemplated that the polypeptides, antibodies, and other active compounds of the present invention may be used to treat various immune related diseases and conditions, such as T cell mediated diseases, including..." [Emphasis added.] A list of exemplary conditions are set forth on the last paragraph of page 59 and the first paragraph of page 60. Subgeneras and specific common immune and immune-related disorders are discussed on pages 60-63. The entire DeSauvage document is drawn to "Type I cytokine Receptor TCCR" (see title). TCCR is also known as WSX-1. As stated of record, DeSauvage specifically teaches methods of treatment of diseases characterized by immune hyperactivation (see pages 59-63) using TCCR (WSX-1) polypeptides and antibodies, including agonist antibodies. Additionally, DeSauvage also specifically contemplates inhibition of molecules with proinflammatory properties (i.e. to treat immune hyperactivity) at p. 63, line 36. Applicant's attention is also drawn to the abstract of the publication.

Applicant argues that it is illogical to suggest that DeSauvage teaches administration of IL-27 or any other IL-27R agonist to treat a person with immune hyperactivity (Remarks, p. 5). Applicant argues that DeSauvage contemplates inhibition (antagonization) of molecules with proinflammatory properties, but does not teach how to inhibit proinflammatory molecules by the claimed method (Remarks, p. 5). Applicant's arguments have been considered, but they are not persuasive.

As stated of record, DeSauvage also specifically contemplates inhibition of molecules with proinflammatory properties (i.e. to treat immune hyperactivity) at p. 63, line 36. Immune related diseases are defined on p. 8 of the specification as a disease in which a component of the immune system in a mammal caused, mediates, or otherwise contributes to morbidity in a mammal. Immune-mediated inflammatory diseases, non-immune mediated inflammatory diseases, infectious diseases, immunodeficiency diseases, and neoplasia are included in this definition (see, p. 8) and exemplified by disease name on p. 9. Methods of treatment using TCCR (WSX-1) polypeptides and antibodies to treat various immune related diseases and conditions, including T-cell mediated diseases, such as those characterized by infiltration of inflammatory cells into a tissue, stimulation of T-cell proliferation, inhibition of T-cell proliferation, increased or decreased vascular permeability or the inhibition thereof, are taught, along with exemplary disorders and conditions are disclosed on page 59 and common relevant immune and immune-related disorder are discussed on pp. 60-63.

Applicant argues that "while agonist antibodies of IL-27R may be discussed in DeSauvage, the only use for such agonists taught by DeSauvage is in the differentiation of helper T cells (Remarks, p. 7).

Applicant is reminded that on page 59, under the heading "Methods of Treatment" DeSauvage states that "[i]t is contemplated that the polypeptides, antibodies, and other active compounds of the present invention may be used to treat various immune related diseases and conditions, such as T cell mediated diseases, including..." [Emphasis added.] The agonist antibodies of IL-27R taught by DeSauvage are encompassed in the methods of treatment of immune related diseases and conditions on pages 59-63.

8. Claims 1, 11, 12, 20, 21, 24-26, 74 and 75 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al., WO 97/25425 (17 July 1997), for the reasons of record and for the reasons set forth herein.

Applicant argues that the methods taught by Bennett are not the same as the instantly claimed methods (Remarks, p. 7). WSX-1 is also known as IL-27R. WSX-1 receptor agonist antibodies are taught on pages 4-5. Specifically, Bennett teaches that agonist antibodies "may be used to treat conditions in which an effective amount of WSX receptor activation leads to a therapeutic benefit in the mammal treated therewith" (p. 4, lines 14-18 and lines 33-34). See also, p. 5, lines 18-20 Stimulation of stem/progenitor cells are only one example of conditions in which a WSX-1 agonist antibody may be used. A list of relevant disorders, including disorders characterized by T helper cell hyperactivity are taught at p. 5, lines 25-29. Cardiovascular disorders, osteoarthritis, diabetes mellitus (Type II diabetes), and insulin resistance, are a few of the disorders recited by Bennett on page 5, lines 25-29 that are also recited in instant claim 21. Instant claim 21 is dependent on claim 20, which is, in turn, dependent on claim 1. The disorders taught by Bennett are encompassed within Applicant's own definition of immune hyperactivity as further limited and defined by claims 20 and 21, unless claims 20 and 21 are improperly dependent or lack proper antecedent basis from instant claim 1. Clarification from Applicant in this regard is required. Bennett also teach dermatological disorders, which would broadly encompass scleroderma, a T helper cell mediated immune disorder characterized by T helper cell hyperactivity. SLE is taught at page 6, line 18. The WSX-1 ligands on page 56, include the treatment of insulin sensitivity, cardiovascular diseases, and dermatological disorders, among others (lines 13-21). Compare instant claims 1, 20, and 21, as explained above.

9. Claims 1, 11, 12, 20, 21, 24-26, 74, and 75 remain rejected under 35 U.S.C. 102(e) as being anticipated by Matthews et al., US Patent 7,074,397 B1 (11 July 2006, benefit to 8 January 1996), for the reasons of record and the reasons set forth herein.

Applicant argues that Matthews does not teach the instant patient population (Remarks, pp. 8-9). Applicant argues that while Matthews may teach what an agonist antibody to WSX-1 does, it does not teach or suggest that a patient with immune hyperactivity needs to have WSX-1 stimulated or that such a patient be given a WSX-1 ligand (Remarks, p. 9). Applicant's arguments have been fully considered, but they are not persuasive. Applicant once again asks the examiner to point out where the idea of an agonist antibody of WSX-1 or IL-27R is mentioned specifically in connection with treating immune hypersensitivity (Remarks, p. 9).

As stated of record, Matthews et al., teach methods of using agonist antibodies that bind to the WSX receptor (IL-27R) (column 3, lines 38-40, 46-47; column 14, lines 61-64, column 17, lines 14-16, column 44, line 22; column 80, lines 47-48 and 58-59; and column 45, beginning at line 36 to column 50) in the treatment of autoimmune disorders, hematopoietic disorders, infections, and malignancies (column 50, lines 58-67 to column 51, lines 1-13) (compare recitation of disorders in instant claim 21). Applicant's definition of the patient population includes individuals with the same disorders taught by Matthews as being treatable with agonist antibodies that bind the WSX receptor (IL-27R). Instant claim 21 is dependent on claim 20, which is, in turn, dependent on claim 1. The disorders taught by Matthews are encompassed within Applicant's own definition of immune hyperactivity as further limited and defined by claims 20 and 21, unless claims 20 and 21 are improperly dependent or lack proper antecedent basis from instant claim 1. Clarification from Applicant in this regard is required. Applicant is advised to compare the recited autoimmune thrombocytopenia purpura [i.e. autoimmune vasculitis] (column 51, lines 2-3) and diabetes mellitus (column 51, line 6) with instant claims 21, 74, and 75.

Conclusion

NO CLAIM IS ALLOWED.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647